

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

JAZZ PHARMACEUTICALS, INC.,

Plaintiff,

v.

AVADEL CNS PHARMACEUTICALS,
LLC,

Defendant.

C.A. No. 21-691-GBW

PUBLIC VERSION

JAZZ PHARMACEUTICALS, INC., et al.,

Plaintiffs,

v.

AVADEL CNS PHARMACEUTICALS,
LLC,

Defendant.

C.A. No. 21-1138-GBW

PUBLIC VERSION

JAZZ PHARMACEUTICALS, INC., et al.,

Plaintiffs,

v.

AVADEL CNS PHARMACEUTICALS,
LLC,

Defendant.

C.A. No. 21-1594-GBW

PUBLIC VERSION

**PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION
AND FOR AN ONGOING ROYALTY**

Pursuant to 35 U.S.C. § 283, Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (“Jazz”) hereby move for entry of a permanent injunction against continued infringement by Defendant Avadel CNS Pharmaceuticals, LLC (“Avadel”) of Claim 24 of U.S. Patent No. 11,147,782 (the “’782 patent”) by making, using, or selling Avadel’s Lumryz™ drug product or any product not more than colorably different from Lumryz, based upon:

(1) The jury’s March 4, 2024 verdict (D.I. 578) finding that Claim 24 of the ’782 patent was not invalid for lack of sufficient written description, was not invalid for lack of enablement, and was not invalid for failure to name the correct inventors;

(2) Avadel’s stipulation to infringement of Claim 24 of the ’782 patent (D.I. 550); and

(3) The evidence and argument to be presented to the Court showing that Jazz has suffered and would continue to suffer irreparable harm resulting from Avadel’s infringement of Claim 24 of the ’782 patent by making, using, and selling Lumryz or any product not more than colorably different from Lumryz, which harm cannot be fully compensated through monetary damages, that the balance of hardships weighs in favor of the entry of a permanent injunction, and that the entry of an injunction will not disserve the public interest.

A Proposed form of Order is attached, which excludes from the proposed injunction making, using, and selling Lumryz: (a) for the patients who have been prescribed Lumryz as of the effective date of the injunction conditional on Avadel paying appropriate remuneration to be determined¹; (b) in currently-ongoing clinical trials and studies; (c) to update data in old studies if necessary; and (d) to re-run necessary tests for quality control for regulators or customers.

¹ Jazz requests that such remuneration be set by the Court pursuant to Jazz’s request for an ongoing royalty.

Jazz further requests that the Court award an ongoing royalty, on a quarterly basis, for sales of Lumryz and any product not more than colorably different from Lumryz, of 27% from the March 4, 2024 jury verdict through 2025, 13% from 2026 through 2032, and 3.5% from 2033 through February 2036 applied to future net revenues of Lumryz from: (1) the patients carved out of the permanent injunction; or (2) if the Court denies the injunction, all Lumryz patients in the U.S.

Dated: April 12, 2024

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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[PROPOSED] ORDER OF PERMANENT INJUNCTION AND ONGOING ROYALTY

WHEREAS, following a jury trial, the jury returned a verdict on March 4, 2024 (D.I. 578) finding that Claim 24 of U.S. Patent No. 11,147,782 (the “’782 patent”) was not invalid for lack of sufficient written description, was not invalid for lack of enablement, and was not invalid for failure to name the correct inventors;

WHEREAS, prior to commencement of the jury trial, Defendant Avadel CNS Pharmaceuticals, LLC (“Avadel”) stipulated to infringement of Claim 24 of the ’782 patent (D.I. 550);

WHEREAS, Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (“Jazz”) have moved pursuant to 35 U.S.C. § 283 for entry of permanent injunction against Avadel’s continued infringement of Claim 24 of the ’782 patent by making, using, or selling Avadel’s Lumryz™ drug product or any product not more than colorably different from Lumryz, and the Court has considered all briefing and supporting evidence submitted in connection with Jazz’s motion;

WHEREAS, the Court finds that Jazz has suffered and would continue to suffer irreparable harm resulting from Avadel’s infringement of Claim 24 of the ’782 patent by making, using, and selling Lumryz, which harm cannot be fully compensated through a payment or payments of monetary damages;

WHEREAS, the Court finds that the balance of hardships weighs in favor of Jazz and the entry of an order of injunction; and

WHEREAS, the Court finds that the entry of an order of injunction will not disservice the public interest:

IT IS HEREBY ORDERED THAT:

1. Jazz's motion for a permanent injunction is GRANTED, and that Avadel and each of its officers, servants, employees, attorneys, and any other persons who are in active concert or participation with them, are hereby permanently enjoined from infringing in any way Claim 24 of the '782 patent, by making, using, or selling Lumryz or any product not more than colorably different from Lumryz, through and including the expiration date of the '782 patent, including any U.S. Patent Office extensions granted thereon.

2. Excluded from this injunction are making, using, and selling Lumryz: (a) for the patients who have been prescribed Lumryz as of the effective date of the injunction conditional on Avadel paying appropriate remuneration to be determined¹; (b) in currently-ongoing clinical trials and studies; (c) to update data in old studies if necessary; and (d) to re-run necessary tests for quality control for regulators or customers.

3. For the avoidance of doubt, for the duration of this injunction, while Avadel may continue to use Lumryz in currently-ongoing clinical trials and studies pursuant to paragraph 2(b) above, Avadel may not seek approval from the U.S. Food and Drug Administration for any indication that was not already part of Lumryz's approved product labeling as of March 4, 2024.

4. The undersigned expressly retains jurisdiction to enforce the judgment and permanent injunction pertaining to this action.

¹ Such remuneration shall be set by the Court pursuant to Jazz's request for an ongoing royalty for net revenues for sales of Lumryz at the royalty rate schedule of 27% from the March 4, 2024 jury verdict through 2025, 13% from 2026 through 2032, and 3.5% from 2033 through February 2036.

IT IS SO ORDERED, this _____ day of _____, 2024

Honorable Gregory B. Williams

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[ALTERNATIVE² PROPOSED] ORDER OF ONGOING ROYALTY

² Jazz requests that this alternative proposed order shall only be entered if the Court denies Jazz's request for a permanent injunction.

WHEREAS, following a jury trial, the jury returned a verdict on March 4, 2024 (D.I. 578) finding that Claim 24 of U.S. Patent No. 11,147,782 (the “’782 patent”) was not invalid for lack of sufficient written description, was not invalid for lack of enablement, and was not invalid for failure to name the correct inventors;

WHEREAS, prior to commencement of the jury trial, Defendant Avadel CNS Pharmaceuticals, LLC (“Avadel”) stipulated to infringement of Claim 24 of the ’782 patent (D.I. 550);

WHEREAS, Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (“Jazz”) have moved for an ongoing royalty, on a quarterly basis, for net revenues for sales of Lumryz and any product not more than colorably different from Lumryz since the jury’s March 4, 2024 verdict applying the royalty rate schedule of 27% through 2025, 13% from 2026 through 2032, and 3.5% from 2033 through February 2036; and

WHEREAS, the Court finds that Jazz is entitled to such ongoing royalty:

IT IS HEREBY ORDERED THAT:

Jazz’s motion for ongoing royalties is GRANTED. Avadel is ordered to pay ongoing royalties to Jazz, on a quarterly basis, for net revenues for sales of Lumryz and any product not more than colorably different from Lumryz since the jury’s March 4, 2024 verdict at the royalty rate schedule of 27% through 2025, 13% from 2026 through 2032, and 3.5% from 2033 through February 2036.

IT IS SO ORDERED, this _____ day of _____, 2024

Honorable Gregory B. Williams

CERTIFICATE OF SERVICE

I hereby certify that on April 12, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on April 12, 2024, upon the following in the manner indicated:

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